

1262557

# THE UNITED STATES OF AMERICA

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*December 16, 2004*

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APPLICATION NUMBER: 60/523,103  
FILING DATE: *November 19, 2003*  
RELATED PCT APPLICATION NUMBER: PCT/US04/39032

Certified by



Jon W Dudas

Acting Under Secretary of Commerce  
for Intellectual Property  
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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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60/523103

111903

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
MICHAEL H. CHRISTOPHER J.		WESTON HESSION		CHAPEL HILL, NC RICHMOND, VA	
<input type="checkbox"/> Additional inventors are being named on the separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
A PACKAGE FOR HOLDING AND PROTECTING VIALS					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number <div style="border: 1px solid black; padding: 2px; display: inline-block;">020457</div>					
OR					
<input type="checkbox"/> Firm or Individual Name		Antonelli, Terry, Stout, and Kraus, LLP			
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		2		<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		1		<input checked="" type="checkbox"/> Other (specify) <b>Fee Transmittal Form</b>	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 01-2135					
<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:					

FILING FEE  
Amount\$  
160.00

[Page 1 of 2]

Date 11/19/2003

Respectfully submitted,

SIGNATURE

REGISTRATION NO. 29,621

(if appropriate)

Docket Number: 1299 43298X00

TYPED or PRINTED NAME **Carl L. Brundidge**

TELEPHONE 703 312-6600

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**FEE TRANSMITTAL  
for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 160**Complete if Known**

Application Number	Not yet assigned
Filing Date	November 19, 2003
First Named Inventor	WESTON, MICHAEL
Examiner Name	
Art Unit	
Attorney Docket No.	1299.43298L00

**METHOD OF PAYMENT (check all that apply)**☐ Check ☒ Credit Card ☐ Money ☐ Other ☐ None  
Order☒ Deposit Account:

Deposit Account Number	01-2135
Deposit Account Name	Antonelli, Terry, Stout & Kraus, LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) during the pendency of this application.☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Code	Large Entity Fee (\$)	Small Entity Code	Small Entity Fee (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
<b>SUBTOTAL (1)</b>					160

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

	Extra Claims	Fee from below	Fee Paid
Total Claims	-20** =	x	=
Indep. Claims	-3** =	x	=
Multiple Dependent			=

Large Entity Code	Large Entity Fee (\$)	Small Entity Code	Small Entity Fee (\$)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	43	Independent claims in excess of 3
1203	280	2203	145	Multiple dependent claim, if not paid
1204	88	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

**SUBTOTAL (2) \$**

\*\*or number previously paid, if greater; For Reissues, see above.

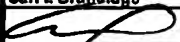
**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity Code	Large Entity Fee (\$)	Small Entity Code	Small Entity Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examination action	
1805	1,840	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1406	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3) (\$)****SUBMITTED BY****Complete (if applicable)**

Name (Print/Type)	Carl L. Brundage	Registration No. (Attorney/Agent)	29,621	Telephone	703-312-6800
Signature				Date	11/19/2003

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## **A PACKAGE FOR HOLDING AND PROTECTING VIALS**

### **BACKGROUND OF THE INVENTION**

The present invention relates generally to packaging for holding and  
5 protecting vials. More particularly the present invention relates to packaging  
for holding and protecting vials in a horizontal manner to permit the labeling  
on the vials to be easily viewed to reduce product errors.

Conventional vial packaging incorporates elements of foam or plastic to  
protect the product in distribution. Such conventional foam or plastic  
10 packaging normally holds the vials in a vertical fashion, enveloping the entire  
product but the cap. Since labeling including product and patient information  
is affixed to the sides of the vials, Conventional vial packaging does not allow  
for such labeling to be easily viewed. Thus, conventional vial packaging can  
induce, for example, medication errors including taking and administering the  
15 wrong medication. As is well known medication errors is a significant problem  
for healthcare institutions (hospitals, etc.) and healthcare providers.

Therefore, packaging is needed that can help to reduces these types of  
errors.

### **SUMMARY OF THE INVENTION**

20 The present invention provides packaging for holding and protecting  
vials in a horizontal manner to permit the labeling on the vials to be easily  
viewed to reduce product errors.

Particularly the present invention provides packaging for holding and  
protecting vials in a horizontal manner including an inner paperboard card  
25 which holds the vials in a horizontal manner and an outer package to which  
the inner paperboard card is releasable attached for enclosing the inner

paperboard card including the vial in a protective cover. The inner paperboard card holds the vials in a horizontal manner by affixing the cap of each vial to a simple click-in paperboard insert formed in a spine of the inner paperboard card. The inner paperboard card by holding the vials in a horizontal manner permits the labeling on the vials to be easily viewed to reduce product errors.

The inner paperboard card and the outer package are each formed from a one piece paperboard which has been cut to have a particular configuration and scored to have fold lines at various preset locations on the paperboard. Each of the inner paperboard card and the outer package is folded along the fold lines according to a preset sequence so as to form the respective element.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and a better understanding of the present invention will become apparent from the following detailed description of example embodiments and the claims when read in connection with the accompanying drawings, all forming a part of the disclosure of this invention. While the foregoing and following written and illustrated disclosure focuses on disclosing example embodiments of the invention, it should be clearly understood that the same is by way of illustration and example only and the invention is not limited thereto, wherein in the following brief description of the drawings:

Figs. 1A and 1B are diagrams illustrating the inner paperboard card and the outer package and how they cooperate with one another according to the present invention; and

Figs. 2A and 2B are diagrams showing the configuration of the one piece paperboards from which the inner paperboard card and the outer package are formed.

#### DETAILED DESCRIPTION OF THE INVENTION

5 Figs. 1A and 1B are diagrams illustrating an inner paperboard card 10 and an outer package 20 and how they cooperate with one another according to the present invention.

The present invention as illustrated in Figs. 1A and 1B provides packaging for holding and protecting vials in a horizontal manner including the  
10 inner paperboard card 10 which holds the vials in a horizontal manner and the outer package 20 to which the inner paperboard card 10 is releasable attached for enclosing the inner paperboard card 10 including the vials in a protective cover.

The inner paperboard card 10 holds the vials in a horizontal manner by  
15 affixing the cap of each vial to a simple click-in paperboard insert 1010 formed in a spine 1020 of the inner paperboard card 10. The inner paperboard card 10 by holding the vials in a horizontal manner permits the labeling on the vials to be easily viewed to reduce product errors. The outer package 20 is formed, for example, as an open end box in which the inner paperboard card  
20 10 is inserted. The inner paperboard card 10 is releasable attached to the outer package 20. The outer package 20 provides protection to the vials during shipping and handling.

The inner paperboard card 10 and the outer package 20 are each formed from a one piece paperboard 30 and 40 respectively. Each one piece  
25 paperboard 30, 40 has been cut to have a particular configuration and scored

to have fold lines 3010, 4010 at various preset locations on the one piece paperboard. Each of the inner paperboard card 10 and the outer package 20 is folded along the fold lines 3010, 4010 according to a preset sequence so as to form the respective element.

5           The package as described according to the present invention provides ease-of-use benefits to the consumer and caregiver, while also offering product protection, cost-effectiveness and labeling to the manufacturer. The present invention, a secondary package, allows for vial-packaged products (including, but not limited to, pharmaceuticals) to be held in place in a highly  
10   durable, user-friendly all-paperboard package. Unlike most vial packaging systems, with the invention, vials are held in place in a horizontal manner by affixing the cap of the vial to a simple click-in paperboard insert. With the horizontal positioning, the labeling of each vial can be easily viewed, including barcodes and NDC numbers. The ability to easily check labeling before use  
15   (including, but not limited to, drug administration) helps to reduce product use errors. Medication errors, such as taking the administering the wrong medication, are a significant problem for healthcare institutions (hospitals, etc.) and healthcare providers.

          The package of the present invention also provides patient medication  
20   compliance benefits, as the outer package (a folding carton) is affixed to the inner paperboard card that holds the vials. Patient and healthcare provider education, such as dosing reminders and potential side effect information, are easily visible to the patient or user throughout the drug regimen.

          As per the present invention drugs that are manufactured in a vial  
25   application can be secured to an inner pullout card for convenient access and

product identification by the patient and user. Patient and healthcare information or history can be recorded directly on the package concerning the individual's dose and delivery. This information remains visible throughout the regimen. The two flaps located inside the inner drawer add support to the spine and protection to the vials.

Current vial packaging incorporates elements of foam or plastic to protect the product in distribution. Foam or plastic packaging normally holds vial in a vertical fashion, enveloping all of the product but the cap. The present invention takes a different approach, holding the vials in place in a horizontal manner by securing the cap to the inner card. The present invention has environmental advantages over existing packaging types because it is all paperboard and fully recyclable. Unlike current packaging for vials, information can be printed in advance or written next to each and every vial, so that patients and users are prompted with key dosing information (i.e. "Saturday dose" or "Take with food").

While the invention has been described in terms of its preferred embodiments, it should be understood that numerous modifications may be made thereto without departing from the spirit and scope of the present invention. It is intended that all such modifications fall within the scope of the appended claims.



WHAT IS CLAIMED IS:

1. A package for holding and protecting vials in a horizontal manner comprising:

an inner paperboard card which holds the vials in a horizontal manner;

5 and

an outer package to which the inner paperboard card is releasable attached for enclosing the inner paperboard card including the vial in a protective cover,

wherein said inner paperboard card holds the vials in a horizontal manner by affixing the cap of each vial to a simple click-in paperboard insert formed in a spine of the inner paperboard card.

10

2. A package according to claim 1, wherein said inner paperboard card and said outer package are each formed from a one piece paperboard which has been cut to have a particular configuration and scored to have fold lines at various preset locations on the one piece paperboard.

15

3. A package according to claim 1, wherein each of said inner paperboard card and said outer package is folded along the fold lines according to a preset sequence so as to form the respective element.

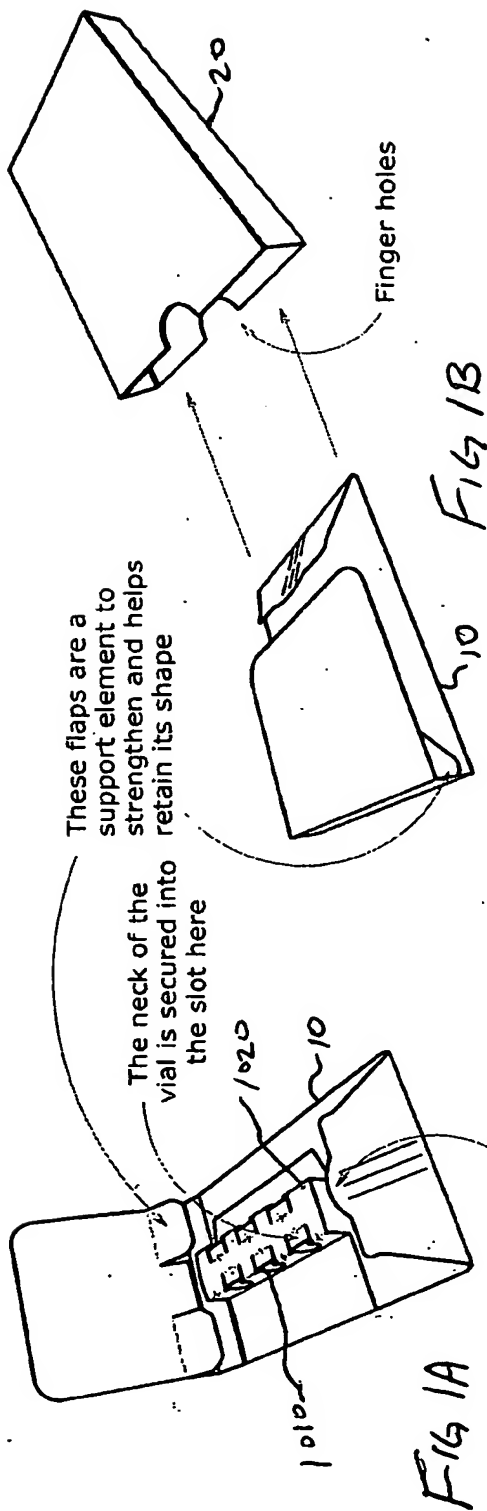
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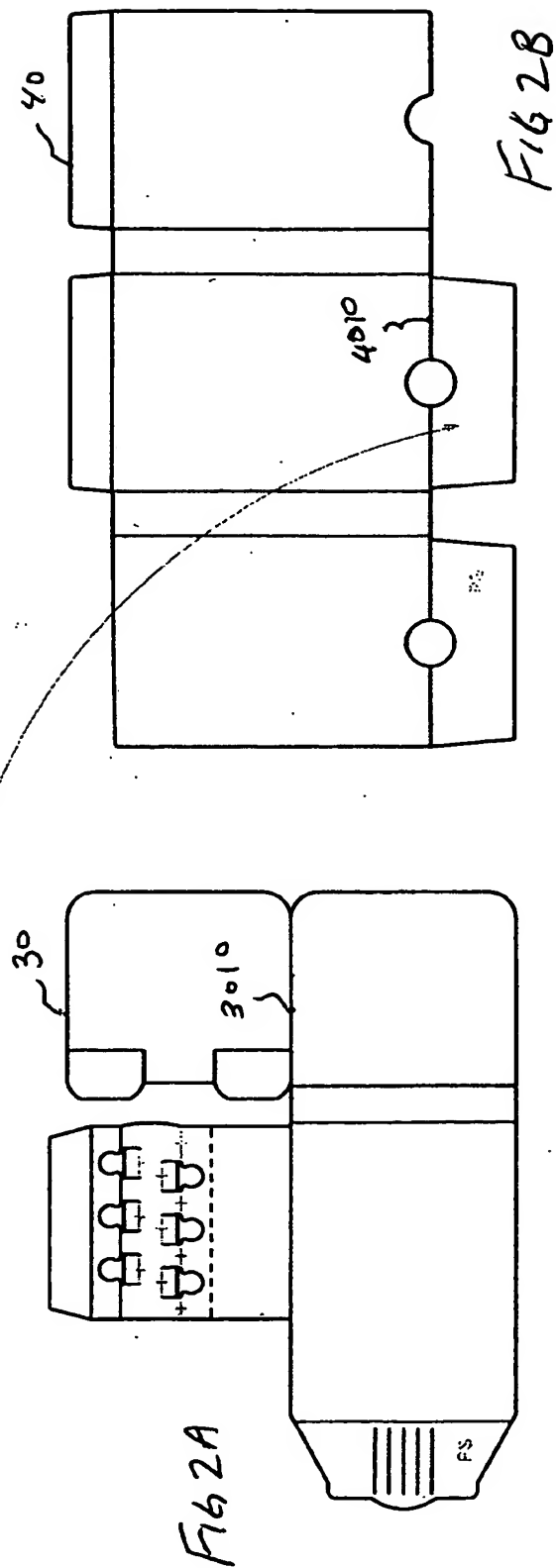
## ABSTRACT

A package for holding and protecting vials in a horizontal manner including an inner paperboard card which holds the vials in a horizontal manner and an outer package to which the inner paperboard card is 5 releasable attached for enclosing the inner paperboard card including the vial in a protective cover. The inner paperboard card holds the by affixing the cap of each vial to a simple click-in paperboard insert formed in a spine of the inner paperboard card. The inner paperboard card and the outer package are 10 each formed from a one piece paperboard which has been cut to have a particular configuration and scored to have fold lines at various preset locations on the paperboard. Each of the inner paperboard card and the outer package is folded along the fold lines according to a preset sequence so as to form the respective element.

15



These elements allows the drawer to open to a set distance



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